REMARKS

This communication is in response to an Office Action mailed on November 30, 2005. In the Office Action, claims 1-37 were pending.

Claims 1-11, 14, 19-30, 33 and 35-37 were rejected under 35 U.S.C. § 102(e) as being anticipated by Sumiya (U.S. Patent No. 6,585,723). Additionally, claims 16-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sumiya. Furthermore, claims 12 and 34 were rejected under 35 U.S.C. as being unpatentable over Sumiya in view of Takahashi et al. (U.S. Patent No. 6,897,964) and claims 13, 15, 31 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sumiya in view of Schmidt et al. (U.S. Patent No. 4,407,008).

Concepts presented in the present application relate to a measurement instrument designed for measurement of central corneal thickness and thus can be used as a pachymeter. A pachymeter can measure central thickness and/or opacity of a cornea with reference to one or more points. The concepts employ confocal optical measurement techniques that can be similar to other devices. However, there are substantial differences and unique characteristics relative to these other devices, which therefore make it materially different from previously-known and previously-disclosed devices.

Sumiya describes a 3D corneal measurement system designed for corneal surgery. Due to the intricate nature of corneal surgery, a topographer is used, rather than a pachymeter. In contrast to a pachymeter, a topographer is concerned with developing an overall contour map of a cornea. Thus, there are several considerations and tradeoffs present where designing a device for pachymetry versus topography. Sumiya refers to a "topography apparatus" and specifically mentions that this apparatus is integral with a surgical system. The main purpose of this topographer is to provide 3D data during surgery as to the ablation characteristics of the surgical procedure and to provide topographical information in a common frame of reference to the surgical system. In order to provide 3D corneal topography data, as is necessary in corneal surgery, this instrument scans the XY dimensions as well as the Z dimension, where Z is the depth position along an axis parallel to or coincident with the fixated patient's line of sight.

Although Sumiya discusses using a confocal instrument, the instrument is fundamentally different than concepts presented in the present application, with significantly different attributes that are characteristic of a device designed for topography, rather than pachymetry. The topography instrument is designed to measure the 3D shape of the cornea, which includes the thickness of the cornea taken at multiple points (over a very large area of the entire cornea) which may undergo ablation during a surgical procedure.

As is typical in confocal systems designed for 3D measurement, the X and Y axes are the "fast" axes, which are scanned at a relatively higher speed using, for example, scanning mirrors 19 and 20 as described in the Sumiya patent. These mirrors are typically galvanometer-driven mirrors or rotating polygonal mirrors. In another approach commonly employed, the X and Y axes may be scanned using a Nipkow disk. A third approach employed in 3D confocal instruments is to use a piezo-actuator system to scan the X and Y axes rapidly. In each of these 3D confocal measurement systems, the Z axis is the "slow" scanned axis. A "slow" Z axis is a necessary compromise for 3D scanning designs because of the relative difficulty of scanning a large objective lens with both rapidity and precision. The scanned mirrors or Nipkow disk may scan quite rapidly in an XY direction due to the type and amount of motion required, and the geometry and mass of their respective construction. However, an objective lens designed to perform high-quality imaging over a large X-Y focal plane field is necessarily large and difficult to scan.

Since these 3D confocal imaging systems support fast imaging in X and Y, they do not rapidly scan in a Z direction.

Thus, a 3D confocal instrument as discussed in Sumiya entails a necessary trade-off with regard to performance as a pachymeter. Increasing Z axis scanning speed in an instrument discussed by Sumiya results in difficulties of 3D data acquisition and position sensing. If the Z axis scanning speed is fast with respect to any relative motion which may occur between the patient's cornea and the instrument, then errors due to such motion will be small. If, on the other hand, the Z axis scanning speed is slower, then appreciable relative motion may occur on the timescale of a single thickness measurement scan time period, which will cause a non-negligible error in the thickness measurement.

A second trade-off relating to 3D measurement involves the working distance, diameter, and size of the objective lens. For a system such as Sumiya which measures an entire corneal surface with a radius of curvature of approximately 7-8mm over a large XY area, the working distance of the lens needs to be very long. The long working distance is needed because the lens must be able to measure the corneal surface elevation at the anterior apex, and at a lower, more peripheral location near the limbus. In order to measure the topography of such a 3D structure without complex optical axis tilting during measurement, a large objective lens is necessary. This large lens is necessary in order to have a large free working distance and a large numerical aperture (NA).. Thus, a system designed for 3D topography over the entire corneal surface is fundamentally limited for the purposes of pachymetry, because a very large lens must be used to ensure both high NA (crucial to confocal thickness measurement accuracy) and a large working distance (crucial to measurement of corneal topography at peripheral locations without hitting the cornea's topographically "higher" locations while doing so). Thus, Sumiya does not teach or suggest utilizing a small, lightweight lens, for example a plastic lens.

Also, the precision with which accurate thickness measurements can be performed using a confocal system is limited by the precision of the system used to monitor the position of the objective lens. For a system which scans the objective lens over a scan stroke length of several millimeters at a rate equal to or greater than 10Hz, the task of tracking the position of said lens to a precision of microns is non-trivial. The Office Action cites that driving circuit 46 monitors a position of the lens, but it is unclear how this monitoring is used in calculation of characteristics of the cornea.

The corneal topographer described by Sumiya, is thus necessarily more complex, cumbersome, and costly than instruments utilizing the concepts presented in the present application. Furthermore, the requirements imposed by 3D measurement necessarily entail trade-offs which detract from the suitability of such a 3D device for the purposes of accurate corneal pachymetry.

Takahishi describes an interferometry-based method for the measurement of thickness of various materials employed in wet-etching processes for semiconductor manufacturing. A galvanometer is used to rapidly scan the reference optical path length of an interferometer, whose optical arms are crossed by an optical coupler, in this case, a 2X2 fiber optic coupler or fused fiber coupler.

Takahishi is cited by the Office Action to describe a fiber coupler as a method of splitting a beam. A fused fiber coupler is a commonly employed passive optical element that is used to mix or split optical signals in a variety of contexts, such as fiber optic communications networks. However, the usage of the fused fiber coupler in Takahishi in combination with Sumiya is simply fundamentally different than the concepts presented in the present application. Measurements in Takahishi are based on Michelson interferometry, rather than confocal optical sectioning and reflectance measurement. Interferometry and confocal measurement are similar in that they both use an optical splitter, such as a beam splitter cube with a partially-reflective surface, or a fiber coupler.

However, the nature of the measured signal is quite different in confocal measurement. In an interferometer, signal peaks arise when the scanned reference arm's optical path length is the same as the optical path length of the measurement arm, and the coherent light which is subsequently re-mixed at the coupler and returned to the detector exhibits interference effects. Thus, Takahashi does not teach or suggest providing a signal as a function of a position of an objective lens.

In a confocal optical arrangement such as disclosed in the present application, the purpose of the beam splitter is to allow for 3 points (point light source, detector spatial filter, and objective focal point) to be mutually confocal to one another in the optical arrangement, such that light from the light source is uniquely concentrated at the focal point region, and light returned from the focal point region by scattering or reflection is uniquely returned through the detector's spatial filter with high throughput efficiency. In a confocal system, the signal does not depend upon interference effects between a measurement and reference arm, and as such, the coupler functions merely as a spatial re-director rather than an interference mixer. In other words, the function of a splitter or coupler is not to combine measurement and reference beams, but rather, to allow mutual simultaneous spatial confocality of the light source, the detector, and the focal region of the objective lens.

Schmidt describes a system for 2D scanning confocal Raman micro-spectroscopy. A method of electronic amplitude and/or phase control of output signals for the purpose of enhanced contrast is disclosed. The difference (or result of other logical operation such as the dividend) between the output signals from 2 or more detectors (one sensitive to a spectrumspecific wavelength for the substance of interest, and one sensitive to a different wavelength) are used to enhance contrast of the image of the substance of interest. Schmidt's discussion of signal manipulation is thus aimed at noise reduction and contrast enhancement for a spectroscopic signal.

Not disclosed by Schmidt is the concept of using a co-planar detector array (rather than the 1D detector array Schmidt does disclose) and the phase errors from the signals of said co-planar detector array in order to assess the perpendicularity of the optical scan axis relative to the scanned object surface. While Schmidt does specifically mention that it may be possible to use his technique for the "better recognition of object contours," the method and apparatus disclosed cannot be used for accurate assessment of perpendicularity. There is simply no teaching or suggestion of a connection between detector spacing, scanning spot velocity, and the trigonometric transforms necessary to discern perpendicularity information. Thus, the signal phase detection method and apparatus disclosed by Schmidt is not sufficient for use as a scanning perpendicularity assessment and/or correction system.

The present application includes independent claims 1, 19 and 24. Given the discussion above, applicants have amended these independent claims to distinguish them from the cited references.

As amended, independent claim 1 recites an apparatus for measuring characteristics of a substance. The apparatus includes a light source to generate light and a first lens to collimate the light from the light source. The second lens receives the collimated light transmitted through the first lens and is adapted to focus the light into a focal region in the substance. Furthermore, the actuator is operably coupled to the second lens to oscillate the second lens along the axis of the direction of the light and a position sensor is operably coupled to the second lens to sense a position of the second lens. A sensor receives a light reflected from the focal region of the substance and provides a signal indicative thereof as a function of the position of the second lens.

Thus, claim 1 recites subject matter previously recited in claims 11 and 15. Claims 11 and 15 have been amended to recite other features of the present invention. As discussed above, Applicant submits that the cited references, either alone or in combination, do not teach or suggest an actuator and position sensor for a second lens such that a signal is provided as a function of the position of the second lens. The Office Action cites that driving circuit 46 is an actuator that oscillates lens 18. However, col. 7, 11.52-62 of Sumiya describes that lens 18 is "gradually shifted in the direction of the thickness of the cornea". No mention is made of oscillating the lens. Furthermore, no mention is made of using a position of the lens to provide a signal. In fact, it appears that signals are provided as a function of the cornea itself, independent of the position of the lens. As a result, independent claim 1 and dependent claims 2-18 that depend therefrom are believed to be allowable.

Independent claim 19 has been amended in order to recite an apparatus having a light source to generate light. The apparatus also includes means for scanning a plastic objective lens and means for monitoring a position of the objective lens. Furthermore, means for focusing a light throughout a substance at a focal region and means for detecting light reflecting off the substance that is confocal with the focal region to provide a signal indicative of characteristics of the substance as a function of the position of the objective lens are included.

As discussed above, it is submitted that the cited references do not teach or suggest means for scanning a plastic objective lens or means for monitoring a position of the objective lens as recited in claim 19. Furthermore, a signal indicative of characteristics of a substance is not provided as a function of the position of the objective lens. Additionally, independent claim 19 recites a plastic objective lens. As discussed in relation to Sumiya, a large, complex lens is needed for a corneal surgery application such as discussed in Sumiya. Thus, there is no teaching or suggestion of using a plastic objective lens as recited in independent claim 19. As a result, independent claim 19 and dependent claims 20-23, which depend therefrom, are believed to be allowable.

Independent claim 24 has been amended to recite a method of quantitatively measuring characteristics of a cornea including generating light and collimating the light with a first lens. The method further includes focusing light with the second lens into a focal region of the cornea and actuating the second lens along the axis of the direction of light to focus light into the cornea at a rate equal to or greater than 10 hertz. A portion of light is reflected from the focal region of the cornea is sensed and is signal indicative of the portion of light reflected is provided. In order to obtain a suitable amount of information, claim 24 recites that the second lens is actuated at a rate equal to or greater than 10 hertz. As discussed above, Sumiya describes that lens 18 is gradually shifted along the direction of corneal thickness. Thus, there is simply no teaching or suggestion of actuating a lens at a rate equal to or greater then 10 hertz. As a result, independent claim 24 and dependent claims 25-37, which depend therefrom, are believed to be allowable.

In view of the foregoing, Applicant's submit that claims 1-37 are in condition for allowance. Favorable actions is solicited.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

WESTMAN, CHAMPLIN & KELLY, P.A.

By:

Todd R. Fronek, Reg. No. 48,516
Suite 1400 - International Centre
900 Second Avenue South
Minneapolis, Minnesota 55402-3319
Phone: (612) 334-3222 Fax: (612) 334-3312

TRF:rdg